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REMARKS TO HILTON HEAD CONFERENCE OF

THE UNIVERSITY OF SOUTH CAROLINA

SCHOOL OF PHARMACY

JANUARY 11, 1987

Much will be written about the Congress that convened on Tuesday, January 6, 1987. It is the historic 100th Congress of the United States.

For those of us in and out of the Congress who care about public health and health policy, the 100th Congress is an opportunity to renew our commitment to solving our nation's most pressing health problems:

- 35 million Americans who have no form of health insurance;
- The AIDS epidemic and the millions of lives that hang in the balance;
- Health care costs, and particularly those costs not covered by insurance like nursing homes and drugs, that continue to race ahead notwithstanding record low inflation;
- A rapidly aging population that will leave the elderly of the 21st century with overwhelming new health care needs

that we are not prepared to meet.

This small list constitutes the most difficult of the matters that must be addressed. There are many more. The task ahead is large, but I enter the 100th Congress with a great deal of hope.

I hope for some major and some minor improvements in our public health and health care financing programs -- improvements that many of us have been pressing for throughout the Reagan Administration. I temper my hope, however, with hard reality.

The budget deficit is still with us, influencing every health policy decision we make. Budget cutting mania produces short-sighted savings. We make cuts in reimbursement rates for hospitals, doctors and pharmacists without full recognition of the potential long-run damage to the quality and availability of care. Next year's deficit reduction targets confound our efforts to be ready for nursing home care in the year 2000 and the immediate health care needs of the AIDS victims and the uninsured.

The other stark reality is that the Administration attacks even the proposals of its own health experts -- like Secretary Bowen's catastrophic care suggestion and the Public Health Service's recommendations for greater AIDS research, education and treatment.

In lieu of these constructive proposals, ~~the President and~~ OMB would require strict Administration adherence to unacceptable, but familiar,

attacks on current programs:

- o Cap the federal contribution to the Medicaid program and leave new and predictable health care costs to be borne totally by the states.

- o Raise Medicare premiums and ~~delay eligibility~~. Spare Dom on health problems + health care.

The Congress has rejected these proposals before, and the Administration knows that. This exhibits once more the leading strategy of the Administration budget makers -- construct unacceptable and unworkable budgets and legislation and then leave the Congress to clean up the numbers and the programs.

Many are predicting that the 100th Congress will simply repeat the budget battles of the last six years. While I, too, fear a repetition of past budget battles, I find an increasing awareness that some health care problems can and must be addressed.

DRUG ISSUES

In the field of pharmaceuticals and health care, there were successes and failures in the 99th Congress and there will be much activity in the 100th.

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The 99th Congress finally awakened to the seriousness of the AIDS Epidemic. If the Sixties are remembered for the War and Protest; the legacy of the Eighties will be the Epidemic. ~~And this Administration will be remembered as ignoring all warnings and asking only that the research and treatment needs be met by someone else.~~

Fortunately, the last Congress did not shirk its responsibilities. We significantly increased ~~basic~~ AIDS research and education money, and, in addition, took an important new step in the war on AIDS. We provided $50 million to develop new drugs to treat the deadly disease. ~~While we are providing research dollars that hopefully will pay off someday, the immediate needs for treatment were being ignored by the Federal government.~~ With these new funds, NIH will test candidate drugs and design as-yet-undiscovered ones.

VACCINE COMPENSATION

The Congress also recognized the needs of the few children who suffer from immunizations so that the many can be disease free. We created a childhood vaccine compensation program.

We take our childhood vaccines for granted. They are public health miracles. In 1952, there were 57,000 cases of paralytic polio, last year there were 4.

Our confidence is so great that elementary schools require vaccines for entry. That is sound public policy. Unfortunately,

vaccines are not completely safe; so some children are hurt in the line of public duty. Every year there are serious reactions, including mental retardation, permanent disability and death.

These children have no place to file their grievances or turn for care. To make matters worse, the drug companies that make vaccines are nervous. Progress toward new and potentially safer vaccines has slowed.

The compensation fund is a generous no-fault system to pay for the medical, rehabilitation, and education costs of those children who are injured. If the injury is particularly severe, the program would pay for lost earnings of the disabled child and for the pain and suffering that he or she endures. In turn, the child's ability to sue the manufacturer would be limited.

The compensation fund will be generated by an excise tax on the vaccines. Because the tax committees were bogged down with tax reform, the excise tax was not included in last year's bill. The tax will be considered this year. I am confident that with the new system in place, the Congress will pass the necessary excise tax.

Congress also created a "fast track" for new vaccines. Armed with $20 million, a Congressionally mandated vaccine "czar" at the Department of Health and Human Services will coordinate all government activity, including at FDA. Our goal is to expedite government and joint public-private initiatives in research, development, approval and

procurement.

That is the good news for vaccine-injured children. The bad news is that President Reagan announced his lack of support for the fund when he signed the bill. In spite of the opposition I expect from him, I know the American people want to help the children who are damaged doing their social duty.

DRUG EXPORT

The Congress also passed the long-debated "drug export" legislation. For years, U.S. drug companies have claimed that U.S. jobs are going overseas to make the drugs that Europe approves before we do. In May 1986, the Senate passed an export bill that went far beyond any legitimate claim for relief. The recently passed law has a much more narrow scope.

A U.S. company that has a drug in human clinical trials will be allowed to export that drug from the U.S., prior to its approval here. Export is limited to a statutory list of industrialized countries with drug approval systems that protect their citizens from unsafe products.

The law does not permit export to developing countries. And we did address the often-repeated allegations of mislabeling and dumping by U.S. companies in Third World countries. The Office of Technology Assessment will conduct a two-year study to determine if U.S. companies are properly labeling the drug products they sell overseas.

Medicaid
State option for children + elderly (esp. drug coverage)
tried to elim. co-payment, but failed.

100TH CONGRESS

There will be much legislation in the 100th Congress that this group will care about. I am sure that all of you followed Congressman Dingell's drug diversion bill last year. I expect Congressman Dingell, who chairs the Committee on Energy and Commerce, to reintroduce his bill. That important consumer legislation bogged down in an end-of-the-session dispute with the pharmaceutical companies over the control of free drug samples.

ORPHAN DRUGS

A number of problems with the Orphan Drug Act have been identified and must be addressed. We desparately need additional grant funds for research on drugs that companies will not sponsor.

We also must clarify who has the right to receive the seven years of market exclusivity. Under current law, when two companies simultaneously develop an orphan drug, the first company that is approved gets the right to market the drug and the second gets nothing. We must find a way to reward orphan drug development that does not discourage independent and simultaneous work by a second company.

DRUG COVERAGE

One of the most important out-patient health benefits that is not

covered by Medicare and not usually covered by private insurance is prescription drugs. My immediate concern is for the elderly who are but 11% of the population and yet consume 30% of the drugs.

Out-patient drug costs are the second highest out-of-pocket expense for the elderly -- behind nursing home care. For many who receive nothing but Social Security checks, the choice each month is between their medicine and their rent or food. Our sick elderly citizens deserve far more from us.

Medicare coverage for drugs could be quite expensive, especially by the standards of today's budget. But the failure to follow a doctor's prescription is a "medical catastrophy" just as the extended hospital stay that Medicare doesn't cover is a financial catastrophy. In fact, not taking the necessary drugs could produce the very catastrophic illness we all want to protect our seniors against.

When catastrophic insurance proposals are considered this year, I believe we must include drug coverage in the debate.

AIDS

Without question, the most urgent problem awaiting the 100th Congress is the AIDS Epidemic.

The Public Health Service estimates that within 5 years we may be paying $16 billion a year for AIDS medical care alone -- equal to about

25% of the entire ~~Medicare budget.~~ The National Academy of Sciences says this is a severe underestimate.

A sizable portion of these costs will be Federal costs, especially as private insurers redline those people who have been exposed.

But as best we can tell, there is no serious planning for how these costs will be borne by the Medicaid and Medicare programs. The Health Care Financing Administration is planning budgets as if the need for health services will be steady, not as if we are about to enter a period of greatly increased need for services. w/ new drugs, such as AZT approved by Burroughs-Wellcome, become fully licensed, we will need to think through who will pay for treatment using these drugs on an out patient basis.

GENERIC DRUGS

Prescription pharmaceuticals ~~Brand name generic drugs~~ are essential consumer goods. The pharmaceutical industry that makes them and the wholesalers and pharmacy retailers that distribute them have a peculiar societal obligation. ~~It is no excuse that you are a business or that your for profit status obligates you to your stockholder or yourself.~~

The public needs new breakthrough drugs, ~~and~~ accurate information and drugs, and price competition that makes drugs more accessible. [redacted]

~~One of the most serious challenges of the 100th Congress is the outrageous price hikes and the unprincipled anti-generic campaign by brand name companies and their trade association, the Pharmaceutical~~

Manufacturers Association.

In 1984, when President Reagan signed the generic drug bill, he proclaimed a day when "the American people will save money, and yet receive the best medicine that pharmaceutical science can provide." While the public now has many new generics available, the brand name companies have subjected us to a disinformation campaign that would make Oliver North blush.

The brand name companies supported the 1984 law, which extended the pre-1962 generic approval system to post-1962 drugs. Then, they quietly turned their advertising and public relation experts loose. After making most of the generics consumed for 20 years, they now claim that the approval system does not protect the public from unsafe or ineffective generics.

They challenge the very bioequivalence tests they have used for years and continue to use now. I am impressed that after a vigorous, almost frantic search for bad generic drugs, they find none.

They fund academic physicians to publicly question generics.

They instruct detail men to question not all generics, just that "one that may be bad."

They submit petitions to undercut portions of the 1984 law that they explicitly agreed to.

They want a free-enterprise American economy, except for their drugs.

While telling us that generics are not trustworthy, they raise prices at unprecedented rates. The public is the loser from this double dose of corporate greed.

This is 1987. The brand name companies are fighting a losing war. They are severely jeopardizing their standing and credibility with the American people.

Nine of the top ten selling brand name drugs are now available as generics. Hundreds of newly-approved generic drugs are creating the only kind of war consumers want -- price wars.

The President predicted a billion dollars of consumer savings over a decade. That is conservative. The 1986 Industrial Outlook of the Commerce Department goes further and says that the generic industry will show an increase in sales of more than a billion dollars in 1986 alone, and that by 1990 about 30% of all prescription drugs will be generics.

This is just the beginning of the impact of the 1984 law. As insurance companies, hospitals, and public programs become familiar with possible savings, many will begin to shift to generic products. Total acceptance by the public is inevitable.

DRUG PRICES

In July 1985, my Subcommittee conducted a hearing on the recent unprecedented price increases. Between 1981 and June 1985, the CPI increased 23%. During the same time, manufacturer wholesale prices rose 56%. Many of the top-selling drugs rose even faster.

These enormous increases continued in 1986. Double digit price increases ae still commonplace. My Subcommittee will be conducting another hearing on prices early in the 100th Congress.

At the hearing I intend to receive testimony about the pros and cons of the Canadian compulsory licensing system.

If prices continue to skyrocket, I believe the fundamental balance of our patent system will be distoted. We award monopolies to innovators. But when the innovation is an essential drug, we cannot allow a private enterprise to price sick people out of the market. The Canadian system insures price competition long before the U.S. patent would expire. Their compulsory licensing system and other efforts to hold prices at reasonable levels must now be explored.

MEDICAID REIMBURSEMENT FOR GENERICS

This audience knows that the Medicaid Maximum Allowable Cost (MAC) program was suspended in 1983. The MAC Program was Medicaid's way to

limit reimbursement to pharmacists to the cost of generic drugs, when they were available.

The Department of Health and Human Services has taken long enough with a new proposal. An Administration that proposes $90 billion in Medicare and Medicaid cuts in the next five years certainly should be expeditious in renewing the generic reimbursement program.

Further discussion is unnecessary. Further delay raises serious questions about the motivations of the Department of Health and Human Services. Are they protecting the brand name companies or the Federal government?

If new regulations are not forthcoming, my legislation will be.

CLOSING

As you can see, the 100th Congress will be memorable for more than its number. Legislation will be coming fast and furious. For those inteested in the health care marketplace it will be a decisive year for policy and practical economics.

Thank you.